



Florida Georgia Blood Alliance

Saving Lives Begins At Home

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Jay S. Epstein, MD, Director
Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 400N
Rockville, MD 20852-1448

Dear Dr. Epstein:

I am writing to express one specific concern regarding the regulations of the Prescription Drug Marketing Act of 1987 (PDMA).

As presently structured, a blood center's ability to carry out both its role as a wholesale distributor of blood derivatives and a health care entity will end pursuant to the final rule implementing the Prescription Drug Marketing Act ("PDMA") which was to take effect on December 4, 2000. As discussed fully below, this is clearly contrary to the public health of the local communities served by blood centers. I understand that the agency has re-opened this issue for comments for further consideration.

I have been responsible for therapeutic apheresis operations in two busy blood centers in different cities over a thirty-year period. In each city, there have been instances where the blood center lacked albumin to be used as replacement fluids and had to procure them from the hospital pharmacy. Twice that I can recall this has led to the 25% albumin being diluted with sterile water instead of normal saline. The resulting hemolysis was no surprise, once we had investigated each step of preparations leading up to it. I have not once witnessed a similar incident involving solutions similarly prepared by the blood centers.

My point is that the cGMPs used in blood centers actually work! I'm sure the pharmacists who prepared these solutions understand the physiology as well as anyone, but they did not give consideration to the fluid infusion rates used in these procedures. The blood center staff that prepare the solutions are going to actually use them and have an appreciation for the osmotic needs in the specific circumstances.

There are several more broadly applied examples, being communicated by others, of why blood centers should be allowed to provide pharmaceuticals in conjunction with therapeutic procedures the blood center is conducting. I hope this specific one is sufficiently attention getting, because it surely generates a lot of attention when it happens, and it is an avoidable error!

I appreciate the agency's consideration of issues, ideas and concerns. Please find a way to allow blood centers to do their part in assuring the best patient care possible!

Sincerely,

Dale R. Malloy

Dale R. Malloy
President and Chief Executive Officer

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